

REMARKS

Reconsideration of the above-referenced application is respectfully requested. Claims 1-29 and 31-37 are pending. Claims 1-14 and 27 have been withdrawn from consideration.

The present response is submitted in accordance with the provisions of 37 C.F.R. §1.116 in response to the new arguments raised in the Advisory Action mailed August 28, 2003. The response is submitted to provide the Examiner with the opportunity to consider these remarks prior to appeal. The present response should be read in light of the response filed July 25, 2003 under 37 C.F.R. §1.116.

CLAIMS 26 AND 29

In maintaining the rejection of independent claims 26 and 29 under 35 U.S.C. §103(a) as obvious over Uo et al. (J. Ceram. Soc. Jpn. 100, p. 426-429) and Hino et al. (US 4,148,689), the Advisory Action mailed August 28 raises three new arguments, namely that (1) Hino et al. suggests that hydrolysis and gel formation when using TMOS as disclosed by Uo et al. can be performed in the absence of an organic solvent such as methanol, (2) the present claims do not exclude an organic solvent as used by Uo et al., and (3) the present specification discloses an implementation that involves forming a sol containing an organic solvent and mixing biological material with the sol

The first argument (i.e., that Hino et al. suggests that hydrolysis and gel formation when using TMOS as disclosed by Uo et al. can be performed in the absence of an organic solvent such as methanol) fails since claims 26 and 29 are not directed to gels formed in the absence of an organic solvent. Rather, claims 26 and 29 are directed to *a solid network defining macropores* or to *gelling a sol to form a gel that has macropores*. Acknowledging that Hino et al. neither describes nor suggests macropores, the Office has turned to Uo et al. (and previously, to US Patent No. 4,148,689 to Nakanishi et al.) for gelation approaches resulting in macropores. However, the approaches in both Nakanishi et al. and Uo et al. are *toxic to vegetative cells*. Indeed, Uo et al. explicitly states that their macroporous gels requires yeast spores because of the durability of yeast spores to organic solvents.

It is therefore irrelevant that Hino et al. suggest that hydrolysis and gel formation can be performed in the absence of an organic solvent because the gel formation in Hino et al. is not gel formation as claimed.

Further, both Uo et al. and Hino et al., as well as a common understanding of the microbicidal properties of alcohols, teach away from the proposed combination. Uo et al. only immobilizes yeast spores in macroporous gels. Hino et al. describes that aqueous sols containing cells and extrusion cast into organic solvents should be freeze-dried immediately after extrusion and, despite such precautions, the relative activity of the cells after casting is reduced. See, e.g., Tables 6 and 7, and col. 14, line 54-col. 16, line 22 of Hino et al. Thus, the only suggestion found in either Uo et al. and Hino et al. is that vegetative cells will not survive the proposed combination, thereby teaching away from the proposed combination. Therefore, any combination of Uo et al. and Hino et al. is improper. *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983).

The second argument (i.e., that the present claims do not exclude an organic solvent as used by Uo et al.) fails because there is no requirement that allowable claims recite the failings of the prior art that make the claims allowable.

Rather, the patentability of claims 26 and 29 is to be determined based on whether or not claims 26 and 29 are obvious. In particular, "[t]he consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art ... and would have a reasonable likelihood of success, viewed in the light of the prior art. ... Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chemical Co.*, 837 F.2d 469 (Fed. Cir., 1988).

As discussed, Uo et al. and Hino et al. provide express teachings away from their combination, and common understanding of the antimicrobial properties of the alcohol in the gelation solution of Uo et al. reinforces that view. Also, the presence of organic solvent deprives one of ordinary skill of a reasonable expectation of success with the combination. Thus, a *prima facie* case of obviousness has not been established.

There is no requirement, statutory or otherwise, that a claim recite the failings of a proposed combination of references. Rather, "[a]n applicant is entitled to claims as broad as the prior art and his disclosure will allow." *In re Rasmussen*, 650 F.2d 1212 (Cust. & Pat.App., 1981). Since a *prima facie* case of obviousness has not been established, it is respectfully submitted that applicant is entitled to claims 26 and 29 as they stand and that any attempt to insist that claims 26 and 29 recite the failings of the references is arbitrary and unjustified in light of the law.

The third argument (i.e., the present specification discloses an implementation that involves forming a sol containing an organic solvent and mixing biological material with the sol) also fails because it is evidence of the non-obviousness of claims 26 and 29. In particular, the fact that an implementation overcomes express teachings away from a combination proposed by the Office is evidence of non-obviousness. Indeed, the suggestion to combine or expectation of success cannot come from Applicant's own disclosure.

Applicant respectfully submits that both Uo et al. and Hino et al., as well as a common understanding of the microbicidal properties of alcohols, teach away from the proposed combination. Thus, combination of the cited references is improper. Further, there is no suggestion to combine the cited references, and a *prima facie* case of obviousness has thus not been established. Applicant therefore respectfully submits that claims 26 and 29, along with the claims dependent therefrom, are patentable over the cited art.

CLAIM 28

In maintaining the rejection of independent claim 28 under 35 U.S.C. §103(a) as obvious over Uo et al. and Hino et al., the Advisory Action raises one new argument, namely that, since the bacterial cell recited in claim 28 can be a bacterial spore, the combination of Uo et al. and Hino et al. is not taught away from by Block (Chapter 12 of the 5th Edition of *Disinfection, Sterilization, and Preservation*).

This contention neglects the fact that neither Uo et al. nor Hino et al. describes or suggests a bacterial spore immobilized within a macroporous solid network. Indeed, none of the species immobilized by either Uo et al. or Hino et al. are bacterial spores. In effect, the maintenance of the 35 U.S.C. §103(a) rejection over Uo et al. and Hino et al. based on this contention amounts to requiring the applicants to show teaching away from a combination that is not described anywhere on the record.

Moreover, both Uo et al. and Hino et al., as well as a common understanding of the microbicidal properties of alcohols, teach away from the proposed combination. Any combination of the cited references is thus improper. *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983).

Applicants therefore respectfully submit that a *prima facie* case of obviousness of claim 28 has not been established. Applicants therefore respectfully submit that claim 28 is patentable over the cited art.

CLAIM 15

In maintaining the rejection of independent claim 15 under 35 U.S.C. §103(a) as obvious over Uo et al., Hino et al., Klein et al. (Better Ceramics Through Chemistry: MRS Symp. Proc. Vol. 32, p. 33-39), and Rao et al. (J. Sol-Gel Sci. Tech. 3, p. 205-217), the Advisory Action raises four new arguments, namely that, (1) claim 15 does not exclude organic solvents, (2) claim 15 does not exclude microbial spores such as yeast spores, (3) it is clear from Uo et al. that methanol can be used in combination with yeast and other microbial spores that would have been resistant to methanol, and (4) that a suggestion to combine and a reasonable expectation of success is found in the complete hydrolysis and condensation in high water sols, the increased rate of hydrolysis in high water sols, and the high surface area of gels formed from high water sols.

The first argument (i.e., that claim 15 does not exclude organic solvents) fails because there is no requirement that allowable claims recite the failings of the prior art that make the claims allowable.

As discussed above, the patentability of a claim rejected under 35 U.S.C. §103(a) is to be determined based on whether or not the claim is obvious. There is no requirement, statutory or otherwise, that a claim recite the failings of a combination, or the grounds of an express teaching away from a combination, of references. Rather, "[a]n applicant is entitled to claims as broad as the prior art and his disclosure will allow." *In re Rasmussen*, 650 F.2d 1212 (Cust. & Pat.App., 1981).

The second and third arguments (i.e., that claim 15 does not exclude microbial spores such as yeast spores and that it is clear from Uo et al. that methanol can be used in combination with yeast and other microbial spores that would have been resistant to methanol) also fail because they represent an unjustified shifting of the burden of proof to the applicant. In particular, these arguments would require that Applicant establish with certainty that the proposed combination will not succeed, rather than requiring the Office to establish a suggestion to combine the cited references and a reasonable expectation of success with the combination.

Turning to the cited art, Uo et al. describes the immobilization of yeast spores in macroporous gels formed from sols at 20°C with a molar ratio of water:hydroxy metallate:methanol of 17:1:2 (including the spore suspension). Uo et al.'s sols are already toxic enough that Uo et al. requires yeast spores that are durable to organic solvents.

Klein et al. describes a sol solution that is reacted for 24 hrs. at 80°C with a molar ratio of water:hydroxy metallate:ethanol of 32:1:15.¹ Klein teaches that the excess ethanol (*over seven times* the amount per mole hydroxy metallate used in Uo et al.) is needed to permit solubility of the additional water. None of Uo et al., Hino et al., Klein et al., and Rao et al. describe approaches to avoiding the need for the excess ethanol, leaving the arguments contending that one of ordinary skill would find a suggestion to combine and a reasonable expectation of success based on increasing the toxicity of Uo et al.'s already toxic sols.

There is no requirement that Applicant establish with certainty that the increase in the toxicity of Uo et al.'s sols be sufficient to kill Uo et al.'s yeast spores. Rather, the burden is on the Office to find a suggestion to combine and a reasonable expectation of success in the cited references to establish a *prima facie* case of obviousness. In light of the express teachings of Uo et al. and a common understanding of the antiseptic properties of alcohols, Applicant submits that one of ordinary skill would have find neither a suggestion to combine or a reasonable expectation of success with the proposed combination.

The fourth argument (i.e., that a suggestion to combine and a reasonable expectation of success is found in the complete hydrolysis and condensation in high water sols, the increased rate of hydrolysis in high water sols, and the high surface area of gels formed from high water sols) also fails since the recited properties are irrelevant to any suggestion to combine or any expectation of success. In particular, there is no evidence that one of ordinary skill would rely upon the recited properties to suggest the proposed combination or in any anticipation of success. While the recited properties may be advantageous in certain circumstances, it is entirely unclear why they are desirable in the claimed endeavor.

Further, the reliance on these *de minimus* properties neglects the express teachings away from the proposed combination found in the references themselves. Indeed, the Advisory Action

¹ The 4:1 volume ratio of ethanol to TEOS corresponds to a 15.3:1 molar ratio, assuming an ethanol density of 0.789 g/ml, an ethanol gram molecular weight of 46.07 g/mole, a TEOS density of 0.934 g/ml, and a TEOS gram molecular weight of 208.3 g/mole.

is suggesting that a sol with an increased rate of hydrolysis and an increased toxicity to biological materials is somehow attractive to one of ordinary skill.

It is respectfully submitted that one of ordinary skill would not confine his or her inquiry to the properties recited by the Office but would rather consider the references as a whole and the express teachings away from their combination found therein.

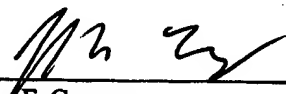
In light of the studies into ethanol activity and express statements in Uo et al. discussed above, not only is a suggestion to combine an a reasonable expectation of success missing, but one of ordinary skill in the art would actually be discouraged from combining the references as suggested. A *prima facie* case of obviousness has thus not been established and applicants respectfully submit that claim 15, and the claims dependent therefrom, are patentable over the cited art.

In view of the above remarks, all of the claims should be in condition for allowance. A formal notice to that effect is respectfully solicited.

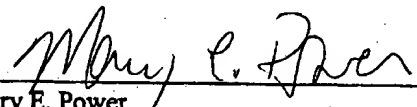
A check in the amount of \$55.00 is submitted herewith along with a petition for a one month extension of time.

Respectfully submitted,

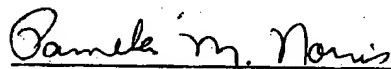
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